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IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR and MICHAEL LOHR,
Respondents/Cross-Petitioners.

ON WRITS OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER/CROSS-RESPONDENT

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INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation ("WLF") is a non-profit public interest law and policy center with more than 100,000 supporters nationwide. WLF regularly appears before federal and state courts to promote economic liberty, free enterprise principles, and a limited and accountable government. To that end, WLF has appeared before this and other federal and state courts in cases involving federal pre-emption issues, arguing that the American economy suffers when multiple layers of government seek simultaneously to regulate the same business activity. WLF appears here by written consent of the parties, on file with the Clerk of the Court.

Medtronic's and the Lohrs' briefs collectively ask whether § 521(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k(a) (1994), pre-empts state law damages claims for manufacturing defect, design defect, and failure to warn with respect to a medical device -- here a pacemaker lead -- that obtained United States Food and Drug Administration ("FDA") clearance for marketing under § 510(k) of the FDCA.[1/] Section 510(k), and the regulations promulgated thereunder, provide one pathway, among several, for a medical device to be cleared for marketing. WLF agrees with Medtronic that FDCA § 510(k) imposes "requirements" meriting pre-emption of the Lohrs' state common law claims.

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1 Because this premarket clearance process is commonly referred to by its section number in the FDCA, WLF retains the § 510(k) nomenclature instead of citing the corresponding section in the United States Code (21 U.S.C. § 360(k) (1994)).

Pre-emption under § 360k(a)[2], however, should not turn on how a medical device enters the market, but rather on the unambiguous language of the immediately preceding section -- § 360j(a) -- which identifies pre-emptive "requirement[s] applicable under the [the FDCA]" as the requirements authorized or established by § 351 (relating to adulterated devices and authorizing the FDA's good manufacturing regulations), § 352 (relating to misbranded devices), § 360 (relating to the registration of devices and including authorization of the 510(k) process), and § 360i (relating to records and reports on devices), *and* any additional "requirements" imposed on a medical device by the FDA at its discretion under § 360d (relating to performance standards), § 360e (relating to premarket approval), and § 360j(g) (relating to exemptions for investigational use devices). 21 U.S.C. § 360j(a) (1994).[3] Under the express language of the FDCA -- which must control the issue of pre-emption -- if any of these requirements is applicable to the device, that requirement pre-empts state common law damages claims for manufacturing defect, design defect, and failure to warn.

SUMMARY OF ARGUMENT

When a statute contains an express pre-emption clause, like § 360k(a), the plain meaning of that clause, considered in light of its statutory context, is the best evidence of Congress' pre-emptive intent. For pre-emption to occur under § 360k(a), four criteria must be satisfied: (1) a state

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2 Unless otherwise stated, a reference to a "section" or "§" is to a section of Title 21 of the United States Code, 1994 Edition.

3 Section 360j(a) is reprinted in the attached Appendix.

"requirement" that (2) "is different from, or in addition to" (3) a federal "requirement" under the FDCA, and that (4) "relates to" the "safety or effectiveness" of the device or to any other matter included in a "requirement applicable" to the device under the FDCA. We provide this Court with a statutory basis for defining a federal "requirement" under the third criterion, and show that these federal requirements pre-empt all of the Lohrs' claims.

Section 360j(a) is the key to defining the federal "requirement applicable to a device" in § 360k(a). Section 360j(a) employs language *identical* to the federal "requirement" in § 360k(a), and expressly identifies those requirements as the FDCA's comprehensive general controls regarding:

- Adulterated devices, including authorization of the FDA's good manufacturing practices regulations (§ 351);

- Misbranded devices, including requirements regarding false or misleading labeling or inadequate warnings (§ 352);

- Registration of manufacturers and their devices, which enables the FDA to evaluate compliance with its safety and effectiveness requirements and authorizes the 510(k) clearance process (§ 360); and

- Continuous evaluation of medical devices by extensive requirements as to the recording and reporting of, among other things, "adverse device experiences" (§ 360i).

Section 360j(a) further identifies FDA discretionary action capable of imposing additional "requirements" under the following FDCA provisions: § 360d (relating to performance standards), § 360e (relating to premarket approval), and § 360j(g) (relating to exemptions for investigational use devices).[4/]

Under well-established principles of statutory construction, the phrase "requirement applicable to a device" should be given the same meaning wherever it appears in the statute. Thus, the comprehensive FDCA requirements identified in § 360j(a) are plainly the "requirement[s] applicable under this chapter to the device" referred to in § 360k(a). While the 510(k) clearance process is but one of these requirements, it is the applicability of "any" of the FDCA requirements identified in § 360j(a) -- i.e., §§ 351, 352, 360, or 360i -- that triggers pre-emption under § 360k(a). These "requirements" collectively create a regulatory web designed to ensure that medical devices are safe and effective; this regulatory web captures all aspects of the manufacture and design of medical devices and disclosures and warnings

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4 Section 360j(a)'s definition of "requirement applicable to a device under this chapter" does not delimit the definition of a State requirement "with respect to a device" to statutory and regulatory requirements. Section 360j(a) only refers to statutory and regulatory requirements because those are the only kinds of requirements created by the FDCA, not because those are the only way "requirements" can be created. Not bound by the FDCA, a State can create a requirement by statute, regulation, or common law. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion) (common law claims create requirements); *id.*, 505 U.S. at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part).

regarding proper and effective use of these devices. Accordingly, a state court judgment finding a manufacturing defect, design defect, or failure to warn is necessarily "different from, or in addition to" the requirements that spin this regulatory web. Because of the comprehensiveness of these requirements, it was reasonable for Congress to incorporate them as the federal requirements that pre-empt all state common law claims for manufacturing defect, design defect, and failure to warn with respect to a medical device subject to the FDCA.

The Eleventh Circuit below invoked an FDA regulation, 21 C.F.R. § 808.1(d) (1995), to narrow Congress' express choice of words in the FDCA. An administrative agency, however, cannot rewrite a statute under the guise of interpreting it. When it does so -- as the FDA did in promulgating 21 C.F.R. § 808.1(d) -- the agency's interpretation is not entitled to any deference, and the Eleventh Circuit's ruling to the contrary is erroneous.

As noted above, the FDCA sets forth extensive federal requirements to prevent the adulteration or misbranding of medical devices, to ensure the proper manufacture, design, and labeling of medical devices, to require registration of medical devices, and to require the reporting of any adverse information about such devices. In 21 C.F.R. § 808.1(d), the FDA blunts the force of Congress' broad statement of pre-emption in § 360k(a) by ignoring § 360j(a)'s identification of these "applicable" federal "requirements," and providing instead that state requirements are pre-empted *only* when the "FDA has established" *specific counterpart* regulations or there are other *specific* requirements applicable to a particular device under the act. The FDA has thus re-written § 360k(a) by adding the modifiers "specific," "particular," and

"counterpart," when no such limiting terms appear in § 360k(a) or § 360j(a).

To the extent they exclude general controls as pre-emptive federal "requirements," these modifiers are inconsistent with the express language of the FDCA, which defines "requirements" to include the requirements identified in § 360j(a). They are also inconsistent with § 360k(a) when read in the context of another FDCA pre-emption provision in which Congress itself chose to use narrowing language to limit the scope of pre-emption. *See* 21 U.S.C. § 360ss (provision providing narrower pre-emption for electronic products subject to the FDCA). Finally, the FDA's redraft of § 360k(a) contravenes the undisputed purpose of the MDA, which added § 360k(a) to the FDCA precisely to encourage innovation by reducing the burden of over-regulation while assuring the public that medical devices will be safe and effective.

ARGUMENT

I. THE PLAIN LANGUAGE OF THE FDCA EVIDENCES CONGRESS' INTENT TO PRE-EMPT STATE LAW DAMAGES CLAIMS FOR MANUFACTURING AND DESIGN DEFECT AND FAILURE TO WARN.

A. The Plain Language of the Statute Governs Whether State Law is Pre-Empted Absent Clearly Expressed Congressional Intent Not to Pre-Empt State Law.

Under the Supremacy Clause of the United States Constitution, state law that conflicts with or frustrates the objectives of a federal statute is pre-empted. *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, ____, 113 S. Ct. 1732, 1737 (1993). Whether a federal statute pre-empts state law depends on congressional intent. *FMC Corp. v. Holliday*, 498 U.S. 52, 56 (1990). "Pre-emption may be either express or implied, and is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Id.* at 56-57 (internal quotation marks omitted). "Evidence of pre-emptive purpose is sought in the text and structure of the statute at issue." *CSX*, 113 S. Ct. at 1737.

If the statute contains an express pre-emption clause, then the task of assessing congressional intent must start with "the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Id.*; *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992). If the clause standing alone is not clear, then congressional intent is determined by ascertaining the meaning of the clause from the text and structure of the statutory scheme in which the clause appears. *See, e.g., Morales*, 504 U.S. at 385-86; *Shaw v. Delta Airlines, Inc.*, 463 U.S. 85, 98 (1983); *Jones v. Rath Packing Co.*, 430 U.S. 519, 532 (1977). When the plain language of the statute as a whole appears to settle the question, the Court looks to legislative history *solely* to determine "whether there is 'clearly expressed legislative intention contrary' to that language, which would require us to question the strong presumption that Congress expresses its intent through the language it chooses." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 432 n.12 (1987).

While this Court has expressed on occasion its reluctance to pre-empt common law damages claims,[5/] it has also recognized that any such hesitation must give way to the language Congress chose to express its intent to pre-empt. Thus "[a]bsent clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive." *Consumer Product Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992); *Park N' Fly, Inc. v. Dollar Park and Fly, Inc.*, 469 U.S. 189, 194 (1985).

B. Section 360k(a) Sets Forth a Four-Part Test for Pre-Emption.

Section 360k(a) provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

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5 *E.g.*, *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

21 U.S.C. § 360k(a).[6/] Thus, to establish pre-emption under § 360k(a), one must demonstrate:

- a state "requirement";
- a federal "requirement applicable . . . to the device" under the FDCA;
- that the state "requirement" is "different from, or in addition to" the federal "requirement applicable . . . to the device" under the FDCA; and
- that the state "requirement" "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the FDCA.

This *amicus* brief addresses the FDCA's identification of the federal requirements that pre-empt state common law claims for manufacturing and design defect and failure to warn.

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6 Section 360k(b) authorizes the FDA to grant exemptions from pre-emption under § 360k(a). No such exemption is applicable here.

C. Section 360j(a) Identifies the Federal "Requirements" Triggering Pre-Emption Under § 360k(a) as Including the FDCA's Requirements Regarding Adulterated and Misbranded Medical Devices, Labeling, Good Manufacturing Practices, Registration of Medical Devices, Record-Keeping, and Reporting.

The FDCA, as amended by the MDA, applies requirements to *all* medical devices independently from the process by which such devices reach the market, and those requirements include the general controls "requirements" identified in § 360j(a) of the FDCA. As noted above, § 360k(a) pre-empts a state requirement with respect to a device "*intended for human use,*" which is different from, or in addition to, "*any requirement applicable under this chapter to the device . . . .*" In the immediately preceding section of the FDCA -- § 360j(a) -- Congress provided that:

> *Any requirement* authorized by or under section 351, 352, 360, or 360i of this title *applicable to a device intended for human use* shall apply to such device until the *applicability of the requirement to the device* has been changed by action taken under section 360c, 360d, or 360e of this title or under subsection (g) of this section, and any *requirement* established by or under section 351, 352, 360, or 360i of this title which is inconsistent with a *requirement* imposed on such device under section 360d or 360e of this title or under subsection (g) of this section shall not apply to such device.

21 U.S.C. § 360j(a) (emphasis added).

Congress thus employed in § 360j(a) language identical to the language it used in expressing the federal requirement for pre-emption in § 360k(a) -- "any requirement . . . applicable to a device." In referring to "[a]ny requirement . . . applicable to a device" in § 360j(a), Congress expressly incorporated the "requirements" authorized or established by § 351 (adulterated devices, which incorporates the good manufacturing practices regulations), § 352 (misbranded devices, which provides the vehicle for all labeling requirements), § 360 (registration of devices, including authorization of § 510(k) clearance), and § 360i (record-keeping and reporting). Congress further provided for additional "requirements" that may be imposed by FDA action taken under § 360d (performance standards), § 360e (premarket approval), and § 360j(g) (investigational device exemption).

Because § 360k(a) employs the identical phrase "any requirement applicable to a device," that language necessarily must also incorporate the requirements of §§ 351, 352, 360, and 360i and any additions to these requirements imposed by discretionary FDA action under §§ 360d, 360e, or 360j(f). *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992) (citing the "basic canon of statutory construction that identical terms within an Act bear the same meaning" and rejecting agency interpretation inconsistent with that meaning); *Sorenson v. Secretary of Treasury*, 475 U.S. 851, 860 (1986) ("The normal rule of statutory construction assumes that identical words used in different parts of the same act are intended to have the same meaning.") (internal quotation marks omitted).

While the FDA's clearance processes under § 510(k) (premarket notification), § 360j(g) (investigational device exemption), and § 360e (premarket approval) are sources

of "requirements" for pre-emption under § 360k(a), it is the applicability of the requirements established by and under §§ 351, 352, 360, and 360i, as they may be supplemented by discretionary FDA action under §§ 360d, 360e, and 360j(g), that *triggers* pre-emption under § 360k(a).[7/] As we show below, these "requirements" create a regulatory web capturing all aspects of the manufacture and design of medical devices, and labeling and warnings regarding their safe and effective usage.

D. The Requirements Listed in § 360j(a) Are Comprehensive to Ensure the Safety and Effectiveness of All Medical Devices.

1. Regulation of Devices Before Enactment of the MDA

Contrary to the Eleventh Circuit's assertion that medical devices were "largely unregulated" before 1976 (Pet. App. 2a), the FDA, in fact, regulated the activities of device manufacturers under the FDCA of 1938. The FDCA of 1938 prohibited the sale of adulterated or misbranded devices, required adequate warnings on device labels, required device manufacturers to permit FDA access to device shipping records, and authorized the FDA to enter and inspect device manufacturing facilities. Federal Food, Drug, and Cosmetic Act, ch. 675, §§ 301, 502, 703,

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7 Section 360j(a) does authorize "changes" to these requirements under sections 360c, 360d, 360e, or 360j(g), but so long as a medical device is subject to "any" of these requirements, a state requirement different from or in addition to these federal requirements is pre-empted.

704, 52 Stat. 1040, at 1042, 1050, 1057 (1938) (codified as amended at 21 U.S.C. §§ 331, 352(f), 373, 374).

2. The MDA Regulatory Scheme

The MDA substantially expanded FDA regulatory power over medical devices by providing for general controls -- the requirements identified in § 360j(a) -- applicable to all medical devices. These provisions of the FDCA set forth a regulatory scheme for all aspects of the manufacture and design of medical devices, and labeling and warnings regarding their proper and safe usage. These requirements, moreover, give the FDA comprehensive oversight once a product enters the market, and the power to remove unsafe, mislabeled, or defective devices from commerce. An examination of that scheme makes it clear why state tort judgments for manufacture or design defect, or failure to warn are necessarily "different from, or in addition to" these federal requirements, and therefore pre-empted.

a. Section 351 -- FDCA Requirements To Prevent The Marketing Of Adulterated Devices

Section 351 imposes requirements by deeming "adulterated" a device that is manufactured or designed defectively. For example, under § 351(h), a device is deemed adulterated if it was not manufactured in conformity with "applicable requirements" of the FDCA's good manufacturing practices provision, § 360j(f)(1). Under the authority of §§ 351(h) and 360j(f)(1), the FDA has promulgated "good manufacturing practices" regulations which are intended to ensure that all devices are manufactured in accordance with generally recognized principles that will result in a device that (1) functions as intended, (2) is safe

and effective, and (3) is in compliance with the FDCA.[8/] Unless the FDA grants an exemption, the GMP regulations require all medical device manufacturers to implement and monitor a comprehensive quality assurance program appropriate to the specific devices they manufacture. 21 C.F.R. § 820.5. The GMP regulations further require that as part of a quality assurance program, manufacturers identify and correct manufacturing and design defects.[9/] In addition, the GMP regulations require manufacturers to investigate complaints about a device (21 C.F.R. § 820.198), to investigate any failure of a device or any of its components to meet performance specifications after the device has been released for distribution (21 C.F.R. § 820.162), and to test each and every change made in the design and manufacture of a device (21 C.F.R. § 820.100(a)(2)).

A device is also deemed adulterated if: (1) it was manufactured under unsanitary conditions; (2) its container is composed of a dangerous substance; (3) it contains an unsafe color additive; (4) it does not comport with an applicable performance standard; (5) it does not comply with an applicable premarket approval requirement; or (6) if a manufacturer fails to comply with a "requirement" for investigational devices. 21 U.S.C. § 351(a), (e)-(g), (i).

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8 On July 18, 1978, FDA issued its Good Manufacturing Practice ("GMP") regulations, 21 C.F.R. Part 820, which became effective on December 18, 1978. 53 Fed. Reg. 8854 (1978).

9 21 C.F.R. § 820.20(a)(3).

b. Section 352 -- FDCA Requirements To Prevent the Marketing Of Misbranded Devices

To ensure that the public is properly instructed and warned as to the safe and effective use of a medical device, § 352 imposes requirements deeming devices "misbranded" under a wide array of circumstances. For example, § 352 deems a device to be misbranded if its labeling is false or misleading or lacks adequate directions for use and warnings against unsafe use. 21 U.S.C. § 352(a), (f). Additionally, a device is "misbranded" if it is dangerous to health when used in the manner recommended or prescribed in its labeling. 21 U.S.C. § 352(j).[10/]

Under § 352(t), a device is "misbranded" if there has been a failure to comply with a "requirement" prescribed in § 360h, which authorizes the FDA to take certain actions when it determines that a device presents "an unreasonable risk of substantial harm to the public health." 21 U.S.C. § 360h(a). Section 360h requires manufacturers to warn health professionals about the risks posed by such devices. *Id.* Furthermore, under § 352(t), a device is deemed "misbranded" if there is a failure to comply with a "requirement" under § 360*l*, requiring post-market surveillance of all devices first marketed after January 1, 1991, and for devices first marketed earlier if the FDA determines that

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10 Under the authority of §§ 351, 352, and 360j, the FDA has promulgated extensive regulatory requirements to ensure appropriate labeling of and warnings about all devices. *See, e.g.*, 21 C.F.R. §§ 801.109(c) (labeling of prescription devices to disclose "any relevant hazardous, contraindications, side effects, and precautions"), 812.5 (investigational devices labeling), and 820.121 (critical devices labeling).

postmarket surveillance of such a device is "necessary to protect the public health." 21 U.S.C. § 360*l*(a).

In addition to the above requirements, § 352 deems a device misbranded if (1) the label does not contain the name and address of the manufacturer, packer, or distributor, and an accurate statement of the quantity or contents; (2) the required information is not placed prominently enough on the label; (3) the established name of the device does not appear in type at least half as large as the proprietary name used; (4) it is manufactured by an unregistered establishment or not listed by a registered establishment; (5) it is a restricted device and its advertisements are false or misleading, or it is not sold or distributed in compliance with the regulations; or (6) it does not comply was an applicable performance standard labeling requirement. 21 U.S.C. § 352(b), (c), (e)(2), (o) - (s).

c. Section 360 -- Device and Manufacturer Registration Requirements; Authorization of § 510(k) Clearance

To aid the FDA in enforcing the FDCA's requirements regarding the manufacture, design, and labeling of devices, § 360 requires all persons who engage in "the manufacture, preparation, propagation, compounding, or processing of a . . . device" to register their establishments with the FDA. 21 U.S.C. § 360(c). Each such establishment is required to re-register annually. 21 U.S.C. § 360(b). To alert the FDA to the existence of devices requiring its regulatory oversight, each person initially registering an establishment with the FDA must also provide a list of all devices manufactured or distributed by the establishment, and must update that list to include devices that are subsequently manufactured or distributed. 21 U.S.C. § 360(j)(1),

(j)(2)(A). Section 360, moreover, subjects every registered establishment to inspection for the express "purposes of enforcement" of the FDCA. 21 U.S.C. §§ 360(h), 374(a)(1).[11/]

d. Section 360i -- Record-Keeping And Reporting Requirements

Section 360i imposes substantial record-keeping and reporting requirements in an effort, among other things, to alert the FDA to adverse information about a device and to allow the manufacturer to correct the device's design, or in the worst case, to enable the FDA to ban the device altogether. Thus, it requires manufacturers to keep records of, and submit reports to the FDA concerning, deaths or serious injuries that may have been caused by a device, as well as any dangerous malfunctions. 21 U.S.C. § 360i(a). Health care facilities, moreover, are required to report to the FDA and the manufacturer "information that reasonably suggests that a device has or may have caused or contributed to the death" or "serious illness" of a patient. 21 U.S.C. § 360i(b).[12/] To prevent defectively designed or manufactured devices from remaining on the market, § 360i(f)(1)(A) requires manufacturers to report removals

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11 Included within § 360 is § 360(k) (§ 510(k) of the FDCA), the pathway to the market for Medtronic's pacemaker lead. The requirement of a 510(k) submission is only one of the many FDCA "requirements" that became applicable to the pacemaker lead from the moment the MDA was enacted.

12 Under the authority of § 360i, the FDA has promulgated extensive medical device record-keeping and reporting requirements. *See, e.g.*, 21 C.F.R. §§ 820.180, 803.31(d), 812.140.

of devices undertaken to reduce health risks posed by the device.

e. Sections 360c, 360d, 360e, And 360j(g) -- Device Classification, Performance Standards, Premarket Approval, And Investigational Devices

Under § 360j(a), the FDA has authority to take action under § 360c (classification of devices), 360d (performance standards), § 360e (premarket approval), and § 360j(g) (exemption for investigational devices[13]) that can change, or make inapplicable, requirements imposed by or under §§ 351, 352, 360, and 360i. As noted earlier, § 360j(a) further vests power in the FDA under §§ 360d, 360e, and 360j(g) to establish device-specific rules that *add* requirements to the general controls in §§ 351, 352, 360, and 360i.

With the enactment of the MDA, all devices became subject to the general controls set forth in §§ 351, 352, 360, and 360i. For purposes of determining whether devices should continue to be subject to the requirements of these general controls, or whether additional requirements should be imposed through the requirements of performance standards or premarket approval, the MDA required the FDA to convene expert panels to classify every medical device, including pre-amendment devices already regulated by the FDA under the FDCA of 1938. Indeed, pre-amendment devices were to be classified within one year

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13 Investigational use devices are experimental devices that are of such medical importance and immediacy to the sick as to require expedited approval and monitoring procedures under the close supervision of medical experts.

after the MDA was funded. 21 U.S.C. § 360c(c)(3).

Section 360c thus requires the FDA to classify all devices into one of three classes, with Class I consisting of devices for which general controls are "sufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A). Class II is home to those devices for which general controls are not sufficient to provide reasonable assurance of the safety and effectiveness of the device, but for which sufficient information exists to establish special controls to provide such assurance. 21 U.S.C. § 360c(a)(1)(B). Such special controls include "performance standards" promulgated pursuant to § 360d -- one of the provisions under which the FDA can impose a supplemental requirement applicable to a device.

Class III, providing for premarket approval, is reserved for devices requiring the greatest scrutiny because neither general controls regulations nor special controls are sufficient to provide reasonable assurance of safety and effectiveness. Section 360e thus supplements the requirements in the general controls of §§ 351, 352, 360, and 360i by requiring premarket approval for devices that the FDA has determined merit the highest level of controls. This does not alter the fact that it is "applicability" of the requirements of the general controls in §§ 351, 352. 360, and 360i -- and not any premarket review process -- that triggers pre-emption of state common law claims for manufacturing and design defect and failure to warn.

3. The FDA Has Comprehensive Powers to Enforce These Requirements.

The FDA has broad enforcement powers against de-

vices that it believes do not comply with §§ 351 and 352. It can detain adulterated or misbranded devices without prior notice to the manufacturer, or seek the seizure and forfeiture of adulterated or misbranded devices. 21 U.S.C. §§ 334(g), 334(a)(2)(D). It can seek an injunction against prohibited conduct or against continued manufacture or distribution of a device that does not comply with §§ 351, 352, 360, 360i, 360e, or 360j(g). 21 U.S.C. § 332.

The FDA can seek felony or misdemeanor criminal prosecution of individuals or corporations for the marketing of adulterated or misbranded devices under §§ 351 and 352. 21 U.S.C. § 333. Civil fines from $15,000 to $1,000,000 for violating a "requirement of this chapter" may also be assessed. 21 U.S.C. § 333(g)(1)(A). The FDA can, among other remedies, also require changes in the labeling of a device (21 U.S.C. § 352(a), (f)(1), (j)), recall a device (21 U.S.C. § 360h(e)(1)), or ban the device altogether (21 U.S.C. § 360f).

E. Claims Alleging Design or Manufacturing Defect or Failure to Warn Are Necessarily "Different From, Or In Addition To" These Federal "Requirements."

The purpose of these comprehensive federal requirements is to ensure that only safe and effective products enter commerce. The requirements are also intended to ferret out unsafe or defective devices already in commerce, in much the same way tort claims cause defective products to be removed from the market.

The first step in ensuring that a product is safe and effective is to require that it be designed properly. To accomplish this, the FDCA first requires that all registered

manufacturers "list" all devices they market. The FDA then begins regulating the design of a listed device, from classifying devices (in order to determine whether, or which, special controls should be applied) down to regulating even what color additives "adulterate" a device. If the FDA determines that general FDCA requirements are not sufficient to ensure the safety and efficacy of a device, the FDA may require that a device satisfy rigorous premarket approval requirements or any other "requirement" it deems necessary.

The FDA must also approve any change in the design of a device that could affect its safety or efficacy. A jury verdict finding a design defect is necessarily a determination that a device's design should be changed to make the device safe and effective. Without pre-emption, whether the design of a medical device should be changed would be within the jury's province, thus supplanting the FDA's approval and supervision of all changes in the design of medical devices that could affect their safety or efficacy.

If, despite these requirements, a defectively designed device enters commerce, the federal requirements outlined above provide systematic opportunities -- in contrast to case-by-case determinations of lay juries -- for identifying those devices and removing them from commerce, if necessary. For example, manufacturers and hospitals must report adverse information about a device, and the FDA has broad inspection powers, including of manufacturer records of adverse information. In addition, all devices are subject to post-market surveillance by the FDA itself to identify unsafe or defective devices.

When faced with a defective device, the FDA can require corrective action, recall the device, or require its

replacement with a properly designed device. The civil and criminal penalties set forth above also give manufacturers strong incentives to design safe devices. Jury verdicts in products liability cases also create incentives for manufacturers -- indeed, this is the *raison d'etre* for imposing liability under a strict liability in tort theory[14/] -- but in a far less comprehensive way than do the requirements administered by the FDA.

Using these same requirements, the FDCA ensures that products will be manufactured safely and effectively. Witness the FDCA's specification of detailed good manufacturing practices, its requirement that all manufacturing establishments register with the FDA, and the FDA's extensive right to inspect every registered manufacturing establishment for, among other things, compliance with these and other manufacturing requirements. Any noncomplying device is deemed "adulterated" and is subject to being seized or recalled. Through the FDCA's comprehensive record-keeping and reporting requirements, defectively manufactured devices are subject to the same continuous review and evaluation by manufacturers, health care professionals, and the FDA as are defectively designed devices. And the FDA's remedies when presented with a defectively manufactured device are equally broad and create the same incentives to manufacturers to produce -- as well as design -- safe and effective devices.

The FDCA contains a panoply of requirements regarding the labeling of devices to ensure that the labeling contains adequate instructions as to a device's proper use and warnings as to its unsafe use. Again, these requirements range from regulating adequate warnings against unsafe use down to specifying every detail of the label's appearance. Indeed, a device is mislabeled (or "misbranded" in the FDCA's parlance) -- and therefore subject to being, among other things, recalled or seized -- if the device is dangerous even when used as recommended (*i.e.*, defectively designed).

The MDA also requires that the FDA convene expert panels to classify every medical device to determine whether the nature of a device merits requirements additional to those in the general controls identified in § 360j(a). A jury verdict finding a manufacturing or design defect or the failure to warn thus displaces the FDA and its expert panel's recommendation as to the level of requirements appropriate for the device at issue.

Given these all-encompassing requirements of the FDCA, a jury verdict finding a design or manufacturing defect, or a failure to warn is necessarily "different from, or in addition to," these federal requirements. Given the comprehensiveness of these "requirements" and the incentives they give manufacturers to design and manufacture safe and effective devices and provide adequate instructions as to safe usage, it was reasonable for Congress, in § 360k(a), to pre-empt state common law claims for design defect, manufacturing defect, and failure to warn.

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14 *See* Guido Calabresi, *The Costs of Accidents* 133-38 (1970).

II. THE ELEVENTH CIRCUIT ERRED IN DEFERRING TO THE FDA'S INTERPRETATION OF § 360k(a) BECAUSE THAT INTERPRETATION REWRITES § 360k(a) AND IS INCONSISTENT WITH OTHER PROVISIONS OF THE FDCA AND CONGRESS' INTENT TO PRE-EMPT.

A. No Deference Is Due to an Agency Interpretation That Conflicts with the Plain Meaning of a Statute.

Reasonable interpretations by an agency of a statute that it administers are entitled to deference from the judiciary if the text of the statute is ambiguous. *National R.R. Passenger Corp. v Boston & Maine Corp.*, 503 U.S. 407, 417 (1992); *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 838, 843 (1984). This deference, however, must not be applied to alter the clearly expressed intent of Congress. *Board of Governors, FRS v. Dimension Fin. Corp.*, 474 U.S. 361, 368 (1986); *Chevron*, 467 U.S. at 843 n.9 ("The judiciary . . . must reject administrative constructions which are contrary to clear congressional intent."). Courts have an obligation to "give effect to the clear meaning of statutes as written." *Estate of Cowart*, 505 U.S. at 476. No deference, therefore, is due to agency interpretations that conflict with the plain language of a statute. *John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank*, 114 S. Ct. 517, 531 (1993); *Demarest v. Manspeaker*, 498 U.S. 184, 190, (1991); *Public Employees Retirement Sys. of Ohio v. Betts*, 492 U.S. 158, 171, (1989).[15] "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43; *Cardoza-Fonseca*, 480 U.S. at 446-48.

B. The Eleventh Circuit's Reliance On FDA Regulation § 808.1(d)

21 C.F.R. § 808.1(d) purports to interpret § 360k(a) by providing, in pertinent part, that:

> State or local requirements are pre-empted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . .

21 C.F.R. § 808.1(d) (1995). Some courts have interpreted this regulation not to conflict with the MDA's pre-emption provision. For example, the Third Circuit has held that even though general control requirements, such as labeling requirements and good manufacturing practices, are "generally applicable regulations," they still "present 'specific requirements applicable to a particular device under the act'" giving rise to pre-emption. *Michael v.*

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15 *Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S. 707 (1985), is inapposite because it involved implied pre-emption, not express pre-emption, and deference to the FDA's interpretation of its own regulations, not to the FDA's interpretation of a statute. *See id.* at 714-15.

Shiley, Inc., 46 F.3d 1316, 1324 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995).

Other courts, pointing to the FDA's use of the words "specific" and "particular" in the regulation, have held, like the Ninth Circuit, that generally applicable FDCA requirements do not "qualif[y] as a '*specific* requirement applicable to a *particular* device.'" *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 (1995) (PMA regulations do not trigger pre-emption). If the Ninth Circuit's interpretation is correct, then the FDA's regulation is in direct conflict with the statute, because it eliminates general control requirements from the scope of the phrase "requirement applicable under this chapter" in § 360k(a)(1).

In the case below, the Eleventh Circuit announced that § 360k(a) is ambiguous, and therefore deferred to the FDA's regulation.[16/] The Eleventh Circuit should not have deferred to the FDA's interpretation of the statute, because that interpretation is contrary to express and unambiguous congressional intent. In fact, 21 C.F.R. § 808.1(d) rewrites the federal and state requirement criteria of

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16 The court offered its own interpretation of the regulation, holding that the term "specific requirements" does not require that the regulation specify the device by name, but only that the regulation be "'restricted by nature' to a particular process, procedure, or device . . . ." Pet. App. 22a. Because GMP requirements are "specific to manufacturing," *id.* at 31a, and "labeling requirements constitute specific requirements for preemption purposes," *id.* at 33a, negligent manufacture and failure to warn claims are pre-empted. The court of appeals found that general control requirements do not "establish any specific design requirements," *id.* at 29a, and therefore concluded that design defect claims are not pre-empted.

§ 360k(a). Under the guise of interpretation, the FDA has added the following boldfaced terms to § 360k(a):

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement **(except for a requirement of general applicability)**[17/] --
>
> (1) which is different from, or in addition to, any **specific counterpart** requirement applicable under this chapter to the **particular** device, and
>
> (2) which relates to the safety or effectiveness of the **particular** device or to any other matter included in a **specific counterpart** requirement applicable to the **particular** device under this chapter.

C. 21 C.F.R. § 808.1(d) Conflicts with the Plain Meaning of the FDCA and Thwarts Congressional Intent.

1. 21 C.F.R. § 808.1(d) is Inconsistent with the FDCA's Definition of the Federal "Requirement."

The FDA's pre-emption regulation provides that state and local requirements are pre-empted *only* when the FDA "has established specific counterpart regulations or there

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17 The Product Liability Advisory Council, Inc.'s *amicus* brief addresses the inconsistency between the statute and this interpretative gloss added by 21 C.F.R. § 808.1(d)(1).

are other specific requirements applicable to a particular device under the act . . ." 21 C.F.R. § 808.1(d).

The FDA's addition of the limiting terms "specific" and "particular" to the statute contradicts the plain meaning of § 360k(a) -- and therefore congressional intent -- because as set forth in Subsection I.C., *supra*, the federal "requirement[s] applicable under this chapter" clearly include, at a minimum, FDCA requirements authorized or established by §§ 351, 352, 360, and 360i.

The FDA's insertion of the word "counterpart" into the MDA's pre-emption provision also conflicts with the FDCA's express language. This term invites a comparison between the state and federal requirements applicable to a device to determine whether they are "counterparts." *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 (5th Cir. 1989) (federal labeling requirements do not pre-empt design requirements imposed by state tort law). The regulation thus imposes a nexus requirement on pre-emption.

If, however, Congress had intended to require a nexus between state and federal requirements as a precondition for pre-emption, then it would have written the statute to require such a nexus. For example, in another pre-emption provision in the FDCA that applies to performance standards for electronic products, Congress imposed just such a nexus requirement:

> Whenever [a certain federal standard is in effect], no State or political subdivision shall have any authority either to establish, or to continue in effect, any standard which is *applicable to the same aspect of performance* of such product . . .

21 U.S.C. § 360ss (italics added). This is a much narrower form of pre-emption: state standards are pre-empted only if they apply to the same aspect of performance as the federal standard. No such limitation appears in § 360k(a), and the FDA is entitled to no deference when it inserts such limiting language into the FDCA. *See Mackey v. Lanier Collection Agency & Serv.*, 486 U.S. 825, 836-37 (1988) (Court will not "imply a limitation on a pre-emption provision in one portion of the statute that Congress made express in another portion of ERISA."); *Russello v. United States*, 464 U.S. 16, 23 (1983) ("'[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'").

2. 21 C.F.R. § 808.1(d) Undermines Congressional Intent by Subjecting Medical Devices to Overburdensome Regulation and to Lay Determinations of Safety and Effectiveness.

The FDA's effort to limit the clear scope of pre-emption under § 360k(a) through its pre-emption regulation is inconsistent with the undisputed purposes of the MDA, which are to encourage innovation by reducing the burden of overregulation, while at the same time ensuring the public that such devices will be safe and effective. H. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). Under the FDA's purported "interpretation" of § 360k(a), pre-emption would be determined on a case-by-case basis and subject to the vicissitudes of a judge, or potentially a jury if 21 C.F.R. § 808.1(d) is interpreted to raise mixed questions of fact and law. One can hardly imagine more burdensome regulation or a less effective means for assuring the public that a medical device is safe and effective where safety and

effectiveness is determined by decision makers without the expertise Congress intended to apply to regulatory decisions relating to devices.

CONCLUSION

For the foregoing reasons, WLF respectfully requests that the judgment of the court of appeals be reversed in part and affirmed in part, and the case remanded with directions to affirm the judgment of the district court.

Respectfully submitted,

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APPENDIX

21 U.S.C. § 360j(a) (1994)

§ 360j. General provisions respecting control of devices intended for human use

(a) General rule. Any requirement authorized by or under section 351, 352, 360, or 360i of this title applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under 360c, 360d, or 360e of this title or under subsection (g) of this section, and any requirement established by or under section 351, 352, 360, or 360i of this title which is inconsistent with a requirement imposed on such device under section 360d or 360e of this title or under subsection (g) of this section shall not apply to such device.